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ALLERGAN USA, INC. and
ALLERGAN INDUSTRIE, SAS

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

REDACTED

[redacted]

Date: July 22, 2014
Time: 9:00 am
Ctrm: 10D
Judge: Hon. Andrew J. Guilford

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I. INTRODUCTION

This patent infringement case relates to two patents that cover hyaluronic acid ("HA") dermal filler compositions and methods for their manufacture, and two competitor products that use the technologies described in those patents—Allergan's Juvéderm XC products and the accused Restylane-L and Perlane-L products. The parties seek construction of only three groups of claim terms between the two patents.

The Court should adopt Allergan's constructions because they are consistent with the plain and ordinary meaning of the claims as informed by the intrinsic record, and reject Defendants' constructions because they violate numerous claim construction rules. For example, the parties dispute the meaning of the term "stable," which is a well-known term with a well understood plain and ordinary meaning. Whereas Allergan's construction—"resists chemical and physical decomposition"—captures the term's plain meaning, Defendants' construction picks and chooses from among the patent's specification to restrict "stable" compositions to those that maintain certain aspects—*i.e.*, pH and sterility—under specific conditions—at least about two months at about 25°C.

Defendants' other proposed constructions wrongly read limitations into the claims from embodiments described into the specification, turn composition claims into product-by-process claims, ignore the principle of claim differentiation, and amount to attempts to narrow the claims to manufacture non-infringement defenses.

Allergan respectfully requests that the Court adopt Allergan's proposed constructions which "stay[] true to the claim language and most naturally align[] with the patent[s'] description of the invention." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

II. NATURE OF THE MATTER

This is a patent infringement case in which Allergan, the manufacturer of the Juvéderm XC line of dermal filler products, has accused Defendants of infringing U.S. Patent Nos. 8,450,475 (the "'475 patent")[1] and 8,357,795 (the "'795 patent")[2] for selling their Restylane-L and Perlane-L dermal filler products in the United States. Allergan filed suit on September 9, 2013, claiming infringement of the '475 patent. On December 6, 2013, Allergan filed an Amended Complaint asserting the '795 patent. The district court approved the Amended Complaint at the February 3, 2014 Scheduling Conference. Fact discovery is underway. A claim construction hearing is set for July 22, 2014. Trial begins August 8, 2015.

III. TECHNOLOGY BACKGROUND

A. Soft Tissue Fillers and Hyaluronic Acid

Soft tissue fillers are gel compositions that are injected beneath the skin to temporarily fill and volumize wrinkles and lines that often develop as a result of environmental factors and aging. (Flanagan Decl., Ex. A ('475 patent) at 1:23-34.) Preferably, fillers should not induce allergic responses, should result in minimal discomfort upon injection, and should be long-lasting so that injections are not too frequent. (*Id.* at 1:35-41.) And fillers must meet the stringent requirements of the FDA because they are regulated as medical devices. (*See id.* at 1:42-45, 54-65.)

Over the past decade in the United States, hyaluronic-acid based soft tissue fillers have dominated the market. (*See id.* at 1:60-65.) Hyaluronic acid ("HA") is a compound made by the body that provides structural support for soft tissues; it is abundant in the skin. (*Id.* at 1:66-2:2.) As shown below, HA is a polysaccharide that consists of repeating D-glucuronic acid and D-*N*-acetylglucosamine discaccharide units. The discaccharide unit is commonly referred to as a monomer,

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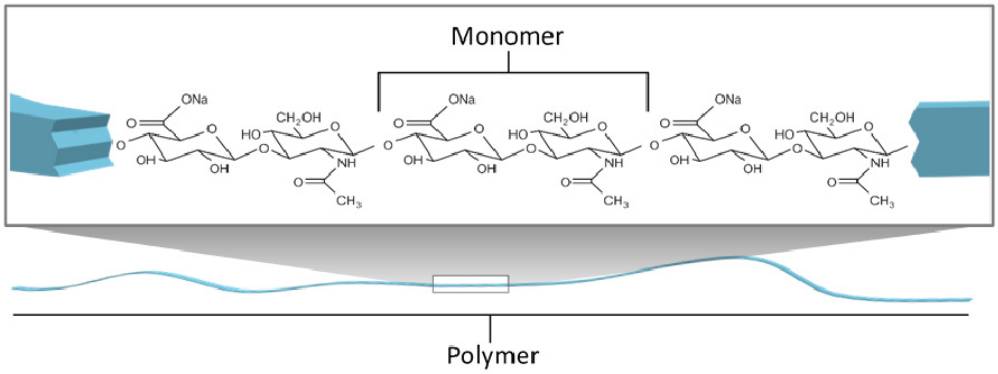
[1] The '475 patent is attached as Exhibit A to the accompanying declaration of Elizabeth Flanagan.

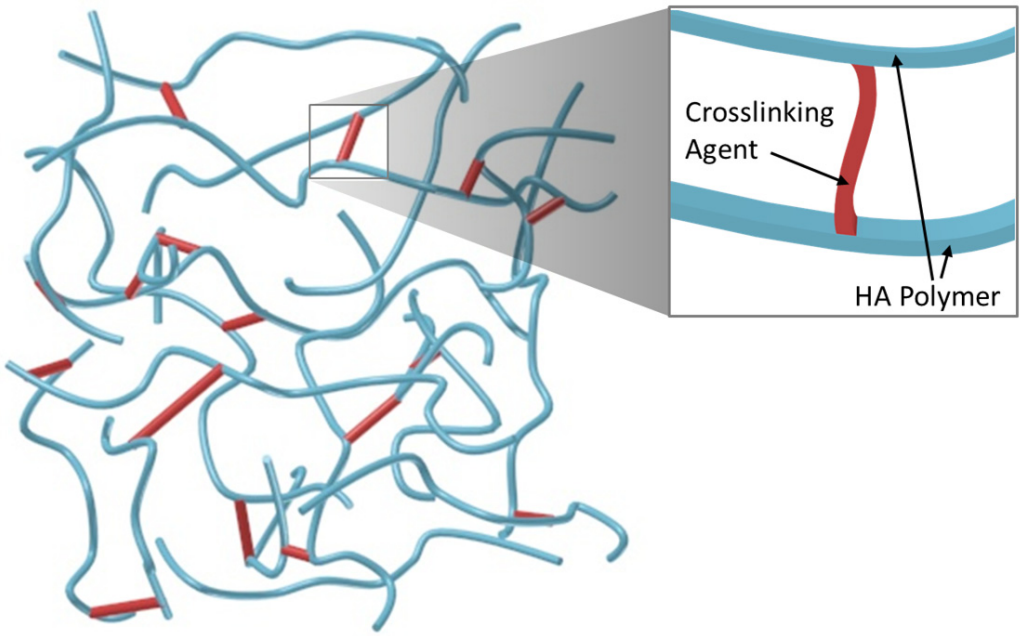
[2] The '795 patent is attached as Exhibit B to the accompanying declaration of Elizabeth Flanagan.

whereas the polysaccharide chain—which can include thousands of disaccharide units—is referred to as a polymer.



HA polymers are both soluble in water and absorb large amounts of water, and thus result in viscous solutions. ('475 patent at 1:66-2:6.)

While HA is an ideal material to serve as a filler based on the foregoing properties, disadvantages of its use include that it is not long-lasting because it is readily degraded by enzymes *in vivo*, and that it can be difficult to inject through a syringe because of its viscous nature. (*See id.* at 2:7-14.) One method scientists have developed to overcome these problems is to link HA polymers together via a chemical compound commonly described as a crosslinking agent. (*Id.* at 2:15-19.) The primary result of this crosslinking process is to create a gel network of HA whereby many HA chains are connected via multiple crosslinking agents, as illustrated below.



The resultant gel network maintains its desirable properties over a much longer period of time in the body before breaking down as compared to individual HA polymers.

B. The Patents-in-Suit, Allergan's Juvéderm® XC Products, and the Accused Products

The claimed inventions of the patents-in-suit are generally directed to HA gel compositions that include HA crosslinked with the crosslinking agent BDDE and include the anesthetic agent lidocaine, which rapidly imparts pain-relieving effect upon injection.[3] Named inventor Dr. Pierre Lebreton began working on these compositions in the mid-2000s. At that time, physicians were commonly treating patients with lidocaine either topically or by injection before injecting the HA filler. Alternatively, some physicians were mixing lidocaine into the HA filler immediately before injection. However, the mixing was not precise and changed the

[3] The patents-in-suit also claim methods of making these compositions but, to date, Allergan has not asserted any method claims because Defendants have not produced enough information for Allergan to assess whether Defendants infringe them.

properties (*e.g.*, viscosity) of the HA filler. In both of these scenarios, lidocaine was used to minimize the pain associated with injection of the HA filler. At that time, manufacturers were not pre-mixing lidocaine into their HA fillers because it was believed that doing so would degrade the HA fillers and thus change their properties. Going against the conventional wisdom, Dr. Lebreton discovered that lidocaine could be added to his BDDE-crosslinked HA fillers without degrading the properties and long-term performance of the products.

Out of this work, Allergan developed its Juvéderm XC line of soft tissue fillers that incorporate lidocaine. Allergan first launched this new generation of HA fillers in Europe where they were met with much skepticism—the industry continued to believe that pre-mixing lidocaine would degrade the HA fillers. But clinical studies showed that Allergan's products did not suffer because of the pre-mixed lidocaine. Other manufacturers were forced to follow Allergan's lead and develop HA fillers with lidocaine to stay competitive. Defendants' Restylane-L and Perlane-L HA fillers are the two competitive products with lidocaine available in the U.S. developed in response to Allergan's innovation.

IV. ARGUMENT

A. Legal Standards for Claim Construction

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude," and as such claim construction must focus on the claim language itself. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Claim terms "are generally given their ordinary and customary meaning" as understood by the skilled artisan at the time of the invention. *Id.* at 1313 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer; and 2) when the patentee disavows the full scope of a claim

term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "The standards for finding lexicography and disavowal are exacting." *GE Lighting Solutions, LLC v. AgiLight, Inc.*, --- F.3d ----, 2014 WL 1704518, at *2 (Fed. Cir. May 1, 2014).

Claim construction begins with the intrinsic evidence—namely, the claim language, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1312–17. The claims provide important guidance both through "the context in which a term is used" and "differences among claims." *Id.* at 1314–15. The specification is "always highly relevant." *Id.* at 1314. However, the specification must be used with care because it is improper to read limitations from embodiments described in the specification into the claims. *Id.* at 1323. The prosecution history may shed light on what a term means, but "it often lacks the clarity of the specification and thus is less useful for claim construction purposes," *id.* at 1317, and it will not limit claim scope unless it contains a "clear and unmistakable" disclaimer. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003). Extrinsic evidence, like dictionaries and treatises, may also be considered, but plays a limited role in the claim construction process. *Phillips*, 415 F.3d at 1317–19.

The claim construction "that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end the correct construction." *Id.* at 1316.

B. The '475 Patent: "Stable"

Disputed Term	Allergan's Proposal	Defendants' Proposal
stable (Asserted Claims 1, 18, 27, 31, 34 of the '475 patent)	resists chemical and physical decomposition	A sterile composition that maintains one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration, after being stored at about 25C for about two months

"Stable" has an unmistakable plain and ordinary meaning, and Federal Circuit "case law is clear, claim terms must be given their plain and ordinary meaning to one of skill in the art." *Thorner*, 669 F.3d at 1367 (citing *Phillips*, 415 F.3d at 1316). Accordingly, Allergan's proposed construction of "stable" is consistent with and explains the term's plain and ordinary meaning. Defendants, by contrast, advance a proposed construction for "stable" that focuses only on certain aspects of a gel's stability properties. Further, Defendants read into the term "stable" the requirement that the claimed gel compositions retain these specific aspects for a specific amount of time—about 2 months—when the gel composition is stored under a specific temperature condition—25° C. There is no basis in the intrinsic record for including these parameters within the construction of "stable." The Court should reject Defendants' construction and adopt Allergan's construction.

1. Allergan's Construction Is Consistent with the Plain and Ordinary Meaning of "Stable" as Used in the Claims

"Stable" has a plain and ordinary meaning that is readily apparent to those in the art. In the context of the claimed inventions, the plain and ordinary meaning of "stable" is simply "resists chemical and physical decomposition." (Flanagan Decl.,

Ex. C at AGNHA00096826 (dictionary defining stable as "not readily decomposing, as a chemical compound"); Flanagan Decl., Ex. D at AGNHA00096820 (dictionary defining stable as "not liable to undergo chemical decomposition")). *See Phillips*, 415 F.3d at 1314 (approving use of general purpose dictionaries to inform well-understood plain and ordinary meaning of claim terms); *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) (approving of the district court's reliance on "several dictionary definitions" to construe a term to "comport[] with [its] plain meaning").

The asserted claims of the '475 patent relate to injectable gels that fill and smooth wrinkles. Because these gels are chemical compositions containing HA and lidocaine, they must be chemically stable—these components must not substantially decompose during the manufacturing processes, during storage, or following injection lest they lose the properties that make them effective at both reducing pain associated with injection in the short term and smoothing wrinkles in the long term. Moreover, the gels require physical stability—the gels cannot be effective at filling and smoothing wrinkles if they do not maintain their physical structure. Indeed, as the '475 patent explains, crosslinked HA gels were created to resist degradation and increase the duration of volumizing effect. ('475 patent at 2:7–16, 2:42–48.) Thus, Allergan's construction of "stable" as "resists chemical and physical decomposition" properly reflects the language and gives full meaning to the claims.

2. Allergan's Construction Aligns with the Specification

The '475 patent's specification takes a broad view of the concept of stability that is consistent with Allergan's proposed construction. To illustrate, the specification discloses that the claimed gels exhibit chemical and physical stability in at least four different circumstances: during sterilization, during homogenization, during storage, and in vivo.

During sterilization, the gel should not be "substantially alter[ed] or degrade[d]" when, for instance, it is autoclaved at high temperatures, pressures, and humidity; exposed to a sterilizing gas; or irradiated. ('475 patent at 11:14–44.) During homogenization, the gel must maintain physical stability when exposed to "mixing, stirring, or beating . . . with a controlled shearing force" to achieve a desired consistency and viscosity. (*Id.* at 10:26–33.) The specification also describes stability during storage for at least 2 months and up to at least 36 months, as well as at ambient temperature (25° C), or elevated temperature (45° C). (*Id.* at 8:4–12.) The patent discloses testing to ensure that lidocaine does not decompose into an undesirable chemical component, 2,6 dimethylaniline, during storage, and that the concentrations of HA and lidocaine remain substantially constant during storage, thus reflecting some parameters that may suggest a gel is stable. (*Id.* at 13:1–54.) Finally, the specification describes gels that "are stable and usable in vivo," referring to the use of crosslinking to minimize in vivo degradation of HA. (*Id.* at 2:31; *see also id.* at 2:7–24.)

All of this discussion demonstrates that the patentee intended a broad use of "stable" to refer to a gel composition that "resists chemical and physical decomposition."

3. The Prosecution History Supports Allergan's Construction

The '475 patent's prosecution history supports Allegan's proposed, plain-and-ordinary-meaning construction—that a "stable" gel "resists chemical and physical decomposition." The Applicant never had to address the meaning of "stable" in the prosecution history because the Applicant and the examiner both understood its plain and ordinary meaning to those in the art. *See In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003) ("As persons of scientific competence in the fields in which they work, examiners . . . are responsible for making findings, informed by their scientific knowledge . . . ."). As a result, there can be no disclaimer of the full scope

of the term "stable" or of any of the embodiments appearing in the specification which demonstrate that "stable" means "resists chemical and physical decomposition." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1322, 1325–26 (Fed. Cir. 2013) (finding no "clear and unmistakable" disclaimer in the prosecution history).

4. Defendants' Proposed Construction Ignores the Plain Language of the Claims and the Intrinsic Evidence

Defendants' proposed construction of "stable" unnecessarily complicates an otherwise straightforward term. As an initial matter, the asserted claims set forth two discrete limitations of the gels: (1) "stable" and (2) "sterile." Yet, Defendants propose to construe the term "stable" to encompass both limitations—"a ***sterile*** composition that maintains [certain aspects]." A proposed construction that subsumes other terms of the claim is improper. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (claims must be "interpreted with an eye toward giving effect to all terms in the claim"); *see also Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1357 (Fed. Cir. 2013) (rejecting a construction for one claim limitation that would render superfluous a separate claim limitation). For this reason alone, the Court should reject Defendants' construction.

What is more, Defendants ignore the specification's broad view of stability, as described above, and instead attempt to limit the broad concept of stability to certain aspects. To support their construction, Defendants will primarily rely on passages of the specification describing that compositions that have been autoclave sterilized or are subject to prolonged storage should maintain one or more of the following aspects to be considered stable: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration. (*See* '475 patent at 3:41–48, 5:39–44.) But these passages do not demonstrate that the patentee intended to act as its own lexicographer and define "stable" in the way Defendants propose, or disavow

the plain and ordinary meaning of "stable." Indeed, to act as a lexicographer and thus depart from the plain and ordinary meaning of a term, a patentee must "clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning" and "clearly express an intent to define the term." *Thorner*, 669 F.3d at 1365 (internal quotation marks omitted). No such qualifying language or intent is contained within the '475 patent's specification. *Compare id.* (describing examples where lexicography and disavowal controlled).

Beyond wrongly limiting stability to certain discrete aspects, Defendants also seek to restrict the concept of stability to certain storage conditions that is otherwise absent from every claim of the '475 patent. (*E.g.*,'475 patent at 8:4–12.) *See Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005) ("Claims of a patent may only be limited to a preferred embodiment by the express declaration of the patentee, and there is no such declaration here.") (internal citation omitted). For instance, Defendants' construction requiring stability at "about 25C" improperly excludes the embodiment of stability at "a temperature up to about 45° C." ('475 patent at 8:10–12.) Moreover, Defendants' construction requiring stability "for about two months" improperly excludes the remaining embodiments of storage stability for "at least about six months, []at least about 9 months, [] at least about 12 months, or at least about 36 months." (*Id.* at 8:6–9.) Because the specification provides no support for limiting the claim as Defendants propose, their construction should be rejected. *See Trebo Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1166 (Fed. Cir. 2014) (finding error in a construction that "improperly imports a limitation into the claim").

The claims make use of the broad plain and ordinary meaning of the term "stable" when describing a gel that "resists chemical and physical decomposition," and the specification and prosecution history demonstrate that the Applicant intended this broad use. Nothing in the intrinsic record is to the contrary.

Therefore, the Court should adopt Allergan's proposed construction of the term "stable" and reject Defendants' construction that impermissibly imports into the claims cobbled-together concepts that do not clearly rise to the level of lexicography or disclaimer.

C. The '475 and '795 Patents: The "Crosslinked HA" Terms

Disputed Term	Allergan's Proposal	Defendants' Proposal
"HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE)"; "hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE)"; "(BDDE)-crosslinked hyaluronic acid" ('475 patent, claims , 18, 27, 31, 34)	HA that forms a macromolecular structure resulting from chemical linking of HA by BDDE	HA that has been covalently modified with BDDE to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%
"hyaluronic acid (HA) component crosslinked with a crosslinking agent" ('795 patent, claim 1)	HA that forms a macromolecular structure resulting from chemical linking of HA by a crosslinking agent	HA that has been covalently modified with a crosslinking agent to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%.

The parties dispute the meaning of the above four claim terms (collectively, the "crosslinked HA terms"), each of which concerns what it means for HA to be crosslinked with a crosslinking agent such as BDDE. Allergan's proposed constructions for these claim terms capture their plain and ordinary meaning as informed by the patents' specifications. Defendants' proposed constructions, by contrast, limit the concept of crosslinked HA in two unsupportable ways: (1) requiring that crosslinked HA is water insoluble, and (2) requiring that crosslinked

HA have a degree of crosslinking falling within a specific range—at least about 2% and up to about 20%. Defendants' construction also introduces unnecessary confusion by describing crosslinked HA as covalently "modified." The Court should reject Defendants' constructions for the crosslinked HA terms and adopt Allergan's.

1. The Intrinsic Record Supports Allergan's Constructions for the Crosslinked HA Terms

The plain meaning of "crosslink" suggests that one material—a crosslinking agent—chemically connects two materials together. Indeed, in common usage, the verb "crosslink" is defined as "to attach by a crosslink," and when used as a noun, crosslink is defined as "a bond, atom, or group linking the chains of atoms in a polymer or other complex organic molecule." (Flanagan Decl., Ex. E at AGHNA00096824.) The concept of crosslinked HA described in the patents is consistent with these plain meanings. The patents describe that crosslinked HA is formed "by reacting free HA with a crosslinking reagent under suitable reaction conditions." ('475 patent at 2:16-18; '795 patent at 2:16-18.) The primary result of this reaction is the linking together of HA polymers by BDDE or another crosslinking agent. Thus, as used in the context of the patents, a person of ordinary skill in the art would understand that when HA is crosslinked with a crosslinking agent, intermolecular bonds or bridges are made between individual HA polymers. Allergan's proposed constructions for the crosslinked HA terms captures the terms' plain meaning because they provide that HA is chemically linked by a crosslinking agent, including, for example, BDDE.

The patents-in-suit also highlight the role of crosslinked HA in the claimed soft tissue filler compositions—namely, that it forms a permanent, macromolecular structure suitable for filling wrinkles and other facial creases. ('475 patent at 4:62-65; 5:5-13; *see also id.* at 1:23-34; 2:7-19; '795 patent at 1:23-34; 2:7-19, 5:43-46,

53-57.) The patents further clarify that crosslinked HA does not merely refer to two HA polymers that are linked, but rather to multiple HA polymers that are chemically interconnected, forming a network of bridged HA polymers, or macromolecular structure. *Id.* As further illustration, the patent distinguishes some HA that is crosslinked from the scope of crosslinked HA. The patents categorize lightly crosslinked HA that is water soluble as "free HA" or "uncrosslinked HA." (*See* '475 patent at 3:7-13; 5:5-13; '795 patent at 3:7-13; 5:53-61.) A skilled artisan would thus understand that, in the context of the inventions, the crosslinked HA terms indicate the formation of macromolecular structure of HA chemically linked by a crosslinking agent such as BDDE, and Allergan's proposed constructions take this into account.

Allergan's proposed constructions correctly incorporate these concepts and no more. Indeed, nothing in the claim language or specification suggests that crosslinked HA must have the specific properties—a certain degree of crosslinking, insolubility in water, or be covalently modified—that Defendants' constructions seek to impose. Rather, the specification simply refers to crosslinked HA, which has the plain meaning described above. For example, in describing a method to prepare crosslinked HA, Example 2 does not specify that the reaction conditions produce crosslinked HA with a degree of crosslinking between 2 and 20%. ('475 patent at 12:20-49; *see also id.* at 2:16-19; *see also* '795 patent at 2:16-19, 13:15-46.) As further example, the patent refers to particles of crosslinked HA without expressly describing them as water insoluble or having a specific degree of crosslinking. ('475 patent at 3:17-19; '795 patent at 3:17-19).

The specifications take a broad, general view of crosslinked HA as used in soft tissue fillers. Allergan's proposed constructions best align with the plain and ordinary meaning of the terms as informed by the specification and should be adopted.

2. Defendants' Proposed Constructions Unnecessarily Limit the Scope of the Crosslinked HA Terms and Lack the Clarity of Allergan's Constructions

Defendants' constructions should be rejected because they would wrongly limit claims to described embodiments and read into the claims properties of crosslinked HA that the record does not describe.

a. "Chemically linked" better describes crosslinked HA than "covalently modified"

Crosslinked HA is more appropriately described as "chemically linked," as Allergan proposes, than as "covalently modified," as Defendants propose. Crosslinking agents are capable of forming two covalent bonds with HA—one at each end of the crosslinking agent. When a crosslinking agent forms one bond with a first HA polymer, and a second bond with a second HA polymer, the two HA polymers are linked together. Only when such linkages are made between HA polymers are permanent structures formed, as taught in the specifications. (*See* '475 patent at 4:62-65; '795 patent at 5:43-46.) Thus, "chemically ***linked***" properly describes the purpose and result of the crosslinking process.

Defendants' proposed constructions' use of "covalently modified" is not as clear as the term "chemically linked." First, the specification never uses that term, or any permutation of it, to describe crosslinked HA. Second, HA that has been "covalently modified" could refer to HA polymers that have reacted with only one end of a crosslinking agent, and thus do not become connected to another HA polymer. That type of modification is not what the specification primarily contemplates in describing crosslinked HA. Indeed, if only one end of the crosslinking agent reacted with HA, there would be no "intramolecular junctions joining the individual polymer molecules … into a permanent structure" as taught in the specification. ('475 patent at 4:62-65; '795 patent at 5:43-46.) Instead there would only be individual polymer molecules linked to BDDE and nothing else—that is not crosslinked HA.

b. Nothing in the record defines crosslinked HA as "water insoluble"

There is no basis in the intrinsic record to construe the "crosslinked HA" terms in part as water insoluble. Neither of the patents-in-suit recites the term "insoluble" nor expressly describes crosslinked HA as water insoluble. The plain meaning of the crosslinked HA terms, as informed by the specification, describes its structure—which his consistent with Plaintiffs' proposed construction. There is no basis to further include in the construction a functional property of crosslinked HA—that is water insoluble—particularly where the record does not expressly use that property to describe crosslinked HA. *Cf. Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1323-24 (Fed Cir. 2002) (providing that it is generally improper to interpret structural claim language as having functional requirements). *See Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 411 F. Supp. 2d 93, 99 (D. Conn. 2006), amended on other grounds, 440 F. Supp. 2d 120 ("Defendant's proposed limitation that the construction require that the 'handle' contain an opening into which fingers can be inserted appears in neither the claim itself, nor the specifications, and thus there is no basis for 'importing' that limitation into the claim construction."). For these reasons, there is no basis to include a functional property of crosslinked HA in the construction of the crosslinked HA terms, and Defendants' proposed construction should be rejected.

c. Nothing in the record requires that crosslinked HA have a degree of crosslinking between about 2% and about 20%

Defendants' proposal to limit the claimed inventions to compositions wherein the crosslinked HA has a degree of crosslinking of about 2% as a lower limit and about 20% as an upper limit violates the well-known claim construction principle that the claims should not be limited to embodiments disclosed in the specification.

Phillips, 415 F.3d at 1323. It would be wrong to include in the construction specific percentages which are not present in the claims and which are not consistent with the entire intrinsic record. Indeed, Defendants' primary intrinsic support for their proposal is a statement that "the degree of crosslinking in the HA component of the present compositions is at least about 2% and is up to about 20%." ('475 patent at 9:25-33; '795 patent at 10:16-30.) But this statement is not the type of statement that trumps the general rule that claim terms should be given their plain and ordinary meaning. *See Thorner*, 669 F.3d at 1365. Further, the specifications additionally describe embodiments wherein the crosslinked HA component has a degree of crosslinking of less than about 5% ('475 patent at 3:22-28, 3:61-64, 4:4-27; '795 patent at 3:22-28, 3:62-65, 4:5-29); less than about 6% ('475 patent at 3:61-64); and about 2% (*id.* at 3:22-28.). The specification also refers to "highly crosslinked" HA but does not set an absolute ceiling on the associated degree of crosslinking, as Defendants propose to do. (*E.g.*, '475 patent at 7:20-23; '795 patent at 8:20-24.) The patents do not specify any degree of crosslinking that the crosslinked HA of the claimed inventions must satisfy. It would be improper to include such limits in the construction.

The claims of the asserted patents demonstrate that it is incorrect to read any specific degree-of-crosslinking requirements into the scope of the crosslinked HA terms. For example, independent claim 1 of the '475 patent recites "HA crosslinked with . . . BDDE" without reference to degree of crosslinking. ('475 patent at 16:40-46.) However, dependent claims 5-7 of the '475 patent do include limitations concerning the degree of crosslinking. (*Id.* at 16:56-61.) Thus, the applicant knew how to limit the properties of the crosslinked HA terms and did so intentionally in certain claims but not in other, broad claims that merely recite crosslinked HA. *GE Lighting Solutions, LLC*, 2014 WL 1704518 at *4 (explaining that limitations from the dependent claims should not be imported into the independent claims.) Perhaps

the best example of this is with respect to independent claim 27 of the '475 patent, which expressly recites "a 1,4-butanediol diglycidyl ether (BDDE)-crosslinked HA having a degree of crosslinking of about 2% to about 20%." ('475 patent at 18:14-21 (emphasis added).) Claim 27 would read as follows if Defendants' proposed construction was applied: "HA that has been covalently modified with BDDE to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20% ***having a degree of crosslinking of about 2% to about 20%***." Such a construction makes no sense. *Allergan, Inc. v. Sandoz Inc.*, 2:09-CV-97, 2011 WL 1599049, at *17 (E.D. Tex. Apr. 27, 2011) (court rejecting defendant's proposed construction which results in repetitive and confusing claim language).

Defendants' construction also would wrongly limit the scope of claims that already contain limitations related to degree of crosslinking by introducing a new lower bound—about 2%. For example, in claims 5-7 of the '475 patent, the degree of crosslinking is less than about 6%, less than about 5% and about 2%, respectively. ('475 patent at 16:56-61.) Defendants' constructions seek to impose a lower bound of about 2% instead of something greater than 0%. Further, none of the claims of the '795 patent recite any degree of crosslinking limitations, yet Defendants would introduce such limitations into all of them. Defendants' approach violates the longstanding rule that "a court may not read a limitation into a claim from the specification," and should be rejected. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004).

The Court should adopt Allergan's proposed constructions, which capture the plain and ordinary meaning of the terms as informed by the patents' specifications, and reject Defendants' proposed constructions which wrongly import limitations from the specification and are inconsistent with the claim language.

D. The '475 Patent: "uncrosslinked HA" and "free HA"

Disputed Term	Allergan's Proposal	Defendants' Proposal
"uncrosslinked HA"; "free HA"	water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA)	water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA) that is added to the crosslinked HA portion of the composition

The parties' dispute over the terms "uncrosslinked HA" and "free HA" concerns the source of water soluble HA in the claimed soft tissue filler compositions. Properly construed, the source of water soluble HA in the claimed compositions is irrelevant—it can be a byproduct or remnant of the gel manufacturing process, added to the composition, or a mixture of those sources. Under Defendants' proposed construction, however, water soluble HA only qualifies as free HA or uncrosslinked HA within the meaning of the claims if it is added to the composition; other sources of water soluble HA would not qualify as free or uncrosslinked HA within the context of the claims. But these are composition claims, meaning that infringement is determined by analyzing the finished product—no knowledge of the manufacturing process is necessary. Defendants' construction would turn these claims into product-by-process claims which is inconsistent with the intrinsic record and would be clear legal error. As set forth below, the intrinsic record does not support limiting free HA or uncrosslinked HA within the meaning of the claims to externally added water soluble HA. The court should therefore reject Defendants' litigation-driven construction and adopt Allergan's.

1. The Specification Supports Allergan's Construction

The parties agree that the '475 patent makes clear that both free HA and uncrosslinked HA refer to water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA). For example, the specification states "free HA includes truly

uncrosslinked HA as well as lightly crosslinked HA chains and fragments, all in soluble form in water." ('475 patent at 3:11-13.) The specification also states, "[f]ree HA as used herein refers to individual HA polymer molecules that are not crosslinked to, or very lightly crosslinked to (very low degree of crosslinking) the highly crosslinked (high degree of crosslinking) macromolecular structure making up the soft tissue filler of the composition. Free HA generally remains water soluble." (*Id.* at 5:5-10.) As such, the parties agree to at least Allergan's proposed construction, which tracks these statements.

Nowhere in these specific descriptions of free HA and uncrosslinked HA nor anywhere else in the specification is there a requirement that water soluble HA be "added to the crosslinked HA portion of the composition" as Defendants would have it. To the contrary, the '475 patent makes clear that the water soluble HA content of the claimed compositions may be present for a variety of reasons.

First, the patent explains that one property of a gel composition—its cohesive nature—is influenced in part by "the amount of residual free HA following crosslinking." ('475 patent at 5:14-21.) The patent further explains that one way to create crosslinked HA is to use as a starting material a gel of free HA. (*Id.* at 4:11-27.) In describing another manufacturing method, the patent explains that the result is an "at least partially crosslinked, HA-based composition." (*Id.* at 6:23-35.) These passages demonstrate that the '475 patent clearly contemplates that the claimed gel compositions can include uncrosslinked HA—water soluble HA—that is a remnant of the starting material of the manufacturing process.

Second, the patent's description of free and uncrosslinked HA— as encompassing "lightly crosslinked HA chains and fragments"—further illustrates that the water soluble content of the gels is not restricted to HA that is added after the crosslinking step in the manufacturing process. (*Id.* at 3:7-13.) The patent describes crosslinking conditions at an elevated pH. (*Id.* at 8:61-9:8; *see also id.* at

2:16-18, 17:1-25, (claims 12-14, describing alkaline crosslinking conditions).) Persons of skill in the art would understand that in such alkaline crosslinking conditions, bonds between the monomeric HA units can break, thereby generating HA fragments that can still be chemically modified by a crosslinking agent during the crosslinking reaction, yielding lightly crosslinked HA fragments. Skilled artisans would further understand that during crosslinking not every HA chain will be chemically linked to the same extent. Thus, lightly crosslinked HA that does not become part of the crosslinked macromolecular structure of HA may also result. The '475 patent takes this into account by describing lightly crosslinked HA chains and fragments as water soluble HA. (*See, e.g.*, *id.* at 3:7-13.) Thus, the '475 patent also clearly contemplates that the claimed gel compositions can include lightly crosslinked, or free, HA that is a byproduct of the crosslinking step of the manufacturing process.

Lastly, in some embodiments, the '475 patent specifies that at least some portion of the free or uncrosslinked HA can be added to the gel composition from an external source. Indeed, Example 2 provides that "[i]f desired, a suitable amount of free HA gel may be added to the HA/lidocaine gel mixture . . . . This free HA gel is then added to the crosslinked HA/lidocaine gel . . . ." (*Id.* at 13:9-10; *see also id.* at 7:29-35 (describing mixing crosslinked HA particles with free HA).) Thus, the '475 patent additionally contemplates that free HA can be added to the gel compositions, whether or not those compositions already contain free HA for some other reason.

Despite the specification's clear guidance that water soluble HA does not have any specific source, Defendants seek to limit it to externally added water soluble HA. With this construction, Defendants attempt to improperly convert these claims into product-by-process claims. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 345 F. App'x 594, 597-99 (Fed. Cir. 2009) (concluding that a district court erred by converting a composition claim to an optically pure chemical compound into a

product-by-process claim by adopting a construction that the optically pure compound was resolved by an HPLC method).

Claim 30 of the '475 patent makes clear why Defendants' construction should be rejected. Claim 30 depends from claim 27, which describes a soft tissue filler composition including "at least about 10% free HA by volume." ('475 patent at 18:14-21.) Claim 30 adds the further limitation that "the composition is prepared by adding free HA to crosslinked HA." (*Id.* at 8:26-27.) Claim 30 explicitly identifies the source of the free HA and is a product-by-process claim. In contrast, claim 27 is a composition claim. Defendants' construction would change the very nature of claim 27 and the other composition claims. *See Medicines Co. v. Dr. Reddy's Labs., Ltd.*, CIV.A. 11-2456 PGS, 2013 WL 64913, at * (D.N.J. Jan. 3, 2013) (rejecting a construction that would turn a composition claim into a product-by-process claim).

Allergan's proposed construction is correct. Defendants' construction is legal error and must be rejected. There is no basis for restricting the free and uncrosslinked HA recited in the claims to solely that which is added from an external source and thereby converting composition claims into product-by-process claims.

2. The Prosecution History Supports Allergan's Construction

The prosecution history of the '475 patent is consistent with Allergan's proposed construction. For example, in characterizing the claims, the Examiner simply stated that "[t]he claims are further directed to the amount of uncrosslinked (HA) is at least 20%," demonstrating that, based on the plain language of the claims, the source of the uncrosslinked HA in the composition was irrelevant to the Examiner. (AGNHA00000589, -713, -3149.)[4]

[4] All citations to the file histories of the '475 and '795 patents refer to the Bates number of the relevant pages in the certified file histories that will be submitted to the Court pursuant to S.P.R. 3.5.2-.3.

The prosecution history contains no "clear and unmistakable" statement that the uncrosslinked/free HA in the claimed inventions must be added from an external source. *Omega Eng'g, Inc.*, 334 F.3d at 1325-26 (Fed. Cir. 2003). Defendants will likely rely on statements made by the Applicant about whether alleged prior art references—namely, Lebreton (US 2006/0194758) and Reinmuller (WO 2005/067944)—disclosed the claimed amount of uncrosslinked HA to support their construction. Yet, although the Applicant made arguments to distinguish those references from the claims, none of those arguments amounted to a disclaimer that the amount of claimed uncrosslinked HA must only be from an external source. Rather, Applicants successfully argued that there was no evidence Lebreton taught uncrosslinked/free HA at all, regardless of its source. (AGHNA00000693-694, 712-15.) And with respect to Reinmuller, there was no dispute that in that reference uncrosslinked HA was added from an external source, and thus no need—and no argument was made—to distinguish the claimed inventions on that basis. (AGNHA00000712-15; AGNHA00003126.) Such statements do not meet to the "exacting" standard for a finding of disavowal. *GE Lighting Solutions*, 2014 WL 1704518, at *2-3 (explaining the standard for prosecution disavowal to attach and examples where it did).

Because there is nothing in the intrinsic record limiting the source of the claimed water soluble HA, the Court should reject Defendants' proposed construction and adopt Allergan's construction.

3. Defendants' Proposed Construction Is Motivated By a Non-Infringement Defense

Defendants' proposed construction for free HA and uncrosslinked HA is also an obvious attempt to remove the accused products from the scope of the claims.

[redacted]

[redacted] Defendants' litigation-driven construction should be rejected.

V. CONCLUSION

For the foregoing reasons, and those to be stated in later briefing and at argument, Allergan respectfully requests that the Court adopt its proposed constructions.

Dated: June 13, 2013

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on June 26, 2014 to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Civ. L.R. 5-3.2.2. Any other counsel of record will be served by electronic mail.

/s/ Elizabeth M. Flanagan

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